

## Nebraska Immunization Program Birthing Hospital Policies and Procedures

The State of Nebraska supplies the birth dose of hepatitis B vaccine at no cost to birthing hospitals willing to participate in this program. The vaccine provided is for every baby born, regardless of insurance status. This is to help reduce barriers to children needing this vaccine as well as reinforce to parents the importance of vaccines to their children. This vaccine can only be used for the birth dose.

To ensure that the publicly funded vaccine is tracked, stored and used appropriately, the following are requirements for providers wishing to participate.

### 1) Provider Enrollment Form

- Form that indicate number of births per year as well as agreement to comply with enrollment requirements
- Forms are distributed in January and due by the end of March
- The Provider Enrollment Form must be signed annually by a person with prescribing authority
- Providers must notify the Nebraska Immunization Program if there is a change in the contact person or NESIIS user
- The vaccine administration fee, if used, will not exceed \$19.82

### 2) Training

- Primary contact in charge of state vaccine will be trained prior to placing their first order of vaccine
- Nebraska Immunization Program staff will provide training

### 3) Nebraska State Immunization Information System (NESIIS)

- Providers will be required to manage inventory and run reports using the NESIIS system.
- Monthly Vaccine Transaction Summary reports are run in NESIIS
- Nebraska Immunization Program staff will provide training

#### 4) Site Visit

The Nebraska Immunization Program staff will perform an annual site visit. The purpose of the site visit is to answer any questions you may have, evaluate vaccine management practices, documentation, and adherence to state program requirements.

The visit will include:

- Questions regarding procedures related to vaccine management and the Vaccine Information Statements (VIS)
- Assessment of storage equipment, temperature monitoring
- Vaccine accountability
- Chart review of vaccine documentation
- State contact will work with you to develop a plan to rectify any discrepancies

#### 5) Vaccine Information Statements (VIS)

It is a federal requirement through the National Childhood Vaccine Injury Act (NCVIA) to distribute a VIS prior to each vaccine administered.

- A current copy of the VIS in several languages may be found at <http://www.immunize.org/vis/>

#### 6) National Child Vaccine Injury Act (NCVIA) documentation laws

NCVIA requires the following to be documented with each vaccine dose:

- Clinic/facility address
- Date vaccine was administered
- Vaccine type
- Vaccine manufacturer
- Vaccine lot number
- Site
- Signature and title of person administering vaccine
- Publication date of VIS
- Date VIS was given to the patient, parent, or legal representative

- More information regarding NCVIA can be found at [http://www.cdc.gov/vaccinesafety/vaccine\\_monitoring/history.html](http://www.cdc.gov/vaccinesafety/vaccine_monitoring/history.html)

#### 7) NCVIA Adverse Event report law

NCVIA requires reporting of:

- Anaphylaxis or anaphylactic shock (7 days)
- Any acute complication or sequela (including death) of the above event (interval – not applicable)
- Events described in manufacturer's package insert as contraindication to additional doses of vaccine (interval – see package insert)
- For more information and the forms visit <http://vaers.hhs.gov/index>

#### 8) Storage and Handling of the Vaccine

Vaccine is sensitive to changes of temperature and so it is important to maintain proper storage and handling of the vaccine to avoid any waste.

Refrigerators must be:

- Appropriate sized based on volume of vaccine
- Combination units need to have separate controls for each section
- Dorm-style units are not allowed
- Be able to maintain year round temperatures of 35-46F (2-8C)

#### 9) Additional Storage Requirements:

- State vaccine must be stored separately from privately purchased vaccine, either by marking boxes or by separating by shelves in storage unit
- Store vaccine in the middle of the refrigerator and away from coils, walls, floor and cold air vents
- Vaccine is never to be stored in the doors, crisper drawers (of household type units) or in the space where the drawers were removed

- Vaccines need to have enough space to allow for air circulation around them and not have a cover placed over them
- Vaccines need to be kept in their original box with lids intact until administration
- Vaccine that is expired or wasted needs to be removed immediately from the storage unit (see below proper handling of vaccine)

10) Thermometers ensure that refrigerators are maintaining the appropriate temperature for vaccine storage:

- Thermometers need to be certified and in current calibration
- Replace thermometers or recalibrate the thermometers every 1-2 years depending on manufacturer's specifications
- Temperature probe placement is optimal in the center of the unit where vaccine is located
- Best practice is to place the temperature probe in a buffer material, such as glycol or glass beads
- Temperatures need to be checked and recorded twice a day
- Action needs to be taken immediately if temperatures are out of range and actions taken recorded

11) Emergency Plan

- Have a written emergency plan for vaccine storage in the event of power outage or equipment failure

12) What to do in the event of a cold chain failure:

- Mark the vaccine "Do Not Use" and store at the appropriate temperature
- Collect the following data
  - Current temperature of the vaccine
  - Minimum or maximum temperatures while it was out of range
  - Amount of time the vaccine was in out of range temperatures
- Call the vaccine manufacturers to determine vaccine viability, the manufacturer will direct you as to whether the vaccine is spoiled or still viable
- Call the Nebraska Immunization Program (402) 471-6423

### 13) Returning expired and/or Spoiled Vaccine

- All expired/spoiled vaccine needs to be returned to the Nebraska Immunization Program within 6 months of expiring/spoiling
- Fill out a Vaccine Return Form and keep a copy for yourself
- Place the vaccine in a box with bubble wrap or a padded envelope with the Return Form (this is the packing slip)
- Mail to: Nebraska Immunization Program

DHHS/Public Health/Immunizations

PO Box 95026

Lincoln, NE 68509-5026

### 14) Vaccine Waste

Vials or syringes that are broken, vaccine drawn up but not administered, needle placed on syringe but not administered or an open vial are all considered waste.

- Fill out a Waste Report and fax in to Nebraska Immunization Program, by the 15<sup>th</sup> of the following month
- Vaccine is then discarded in a sharps container
- Any wasted or spoiled vaccine requires a modification in your inventory in NESIIS

### 15) Replacing Vaccine

Providers may have to replace vaccine if waste is due to negligence.

- Negligence includes:
  - Failing to ensure that vaccines are promptly stored when received
  - Leaving vaccine out of the refrigerator
  - Leaving the refrigerator door open
- You may be suspended from the program until your account is settled

### 16) Ordering Vaccine

- Orders are placed through NESIIS
- Order everything you expect to need until your next ordering cycle
- It is acceptable to keep about a 60 day supply if you order monthly, 90 day supply if you order bi-monthly or quarterly
- Your inventory in NESIIS must be up to date and modified before you place your order

#### 17) Receiving Vaccine Shipments

- Vaccine shipments will arrive according to the days and times you stated on the Provider Enrollment Form that you are open and someone is available to receive vaccine
- If the vaccine has not arrived within two weeks, contact the Nebraska Immunization Program office so that it may be tracked
- Do not refuse a vaccine shipment – always accept vaccine shipments, place them in appropriate storage and contact the Nebraska Immunization Program immediately if your shipment is incorrect (see “Problems with Receiving a Shipment”)
- Check the condition of the vaccines immediately when they arrive and the temperature monitor cards inside the box to assure vaccine has maintained proper temperature during shipping
- Check the shipment log against the vaccine in the box as well as against what you ordered
- Keep packing slips for at least 3 years
- Accept the transfer in NESIIS from the Nebraska Immunization Program to automatically populate your shipment in NESIIS

#### 18) Problems with Receiving a Shipment

- Report any discrepancies immediately to the Nebraska Immunization Program if the vaccine you receive does not match the packing slip or the order you placed in NESIIS
- If the condition of the vaccine is questionable (temp monitor card is activated, ice packs are thawed) mark the vaccine “Do Not Use” and store at appropriate temperature and contact the Nebraska Immunization Program
- If you have any problem with your shipment you must call the Nebraska Immunization Program immediately at (402)471-6423, do not leave a voice mail, you need to speak to a person and explain the situation
- If you cannot locate a person at the Nebraska Immunization Program you must contact McKesson directly at 1-877-836-7123

- The vaccine distributor, McKesson, must be contacted within 2 hours of receipt of vaccine that is compromised

#### 19) Required Reports

The reporting period is from the 1<sup>st</sup> through the end of each month.

- Print inventory Report form NESIIS and use it to count vaccine
- Reconcile inventory in NESIIS by selecting the vaccine and modifying the quantity on hand by choosing the appropriate option
  - Doses administered
  - Doses wasted
  - Doses transferred
  - Doses returned
- Print the Vaccine Transaction Summary Report out of NESIIS and fax to 402-471-6426 by the 15<sup>th</sup> of the following month
- If needed, fax in “Waste Report” along with the Vaccine Transaction Summary

#### 20) Record Retention

Keep these records for at least three years:

- Temperature logs and troubleshooting logs
- Vaccine return reports
- Waste Reports
- Packing lists of vaccine shipped

#### 21) Leaving the Program

- The provider will need to submit a written letter of termination 30 days prior to termination
- All reports must be current to give an accurate account of state vaccine on hand
- All vaccine must be returned to the Nebraska Immunization Program within 30 days of the termination date